IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

IAN WALLACE,
Plaintiff,
vs. No. 4:18-cv-01859-PLC
PHARMA MEDICA RESEARCH, INC.; TRIS PHARMA, INC.; ROXANE LABORATORIES, INC./HIKMA LABS, INC.; and WEST-WARD COLUMBUS, INC.,
Defendants.

VIDEOTAPED DEPOSITION OF

SHABAZ KHAN, M.D.

Taken on behalf of Plaintiffs

November 7, 2019

Reporter: Kimberly A. Harris, CSR

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APPEARANCES

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For the Defendant, Pharma Medica Research, Inc.

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For the Defendants, Roxane Laboratories, Inc., Hikma Labs, Inc., and West-Ward Columbus, Inc.

Mudge Legal Video
By: John Mudge, Videographer

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STIPULATION

IT IS STIPULATED AND AGREED by and between counsel for Plaintiffs and counsel for Defendants that the videotaped deposition of SHABAZ KHAN, M.D., may be taken pursuant to Rule 26(a) of the Federal Rules of Civil Procedure on behalf of the Plaintiff, on November 7, 2019 at the offices of Hinshaw & Culbertson, LLP, 701 Market Street, Suite 1375, St. Louis, Missouri, 63101, before Kimberly A. Harris, a Certified Shorthand Reporter and Notary Public within and for the County of Madison, State of Illinois; that the issuance of notice and dedimus is waived, and that this deposition may be taken with the same force and effect as if all statutory requirements had been complied with.

IT IS FURTHER STIPULATED AND AGREED that any and all objections to all or any part of this deposition except objections as to the form of the question are hereby reserved and may be raised on the trial of this cause; and that the signature of the deponent is not waived.

* * * * * *

MR. MUDGE: We are on the record, and the time is approximately 8:54.

MR. WENDLER: And for the record, we've all agreed to waive the videographer introduction statement.

MS. DREW: Correct.

SHABAZ KHAN, M.D.,

a witness, having been first duly sworn upon oath by the court reporter, testified as follows:

[EXAMINATION]

QUESTIONS BY MR. WENDLER:

Q. Dr. Khan, can you state your full name for us, please?

A. **Shabaz Ali Khan.**

Q. And where do you live sir?

A. **Toronto, it's basically a suburb called Stoufville. It's north of Toronto.**

Q. And you understand we're here to take your deposition to ask you some questions about the company you work for called Pharma Medica Research --

A. **Yes.**

Q. -- Inc.; is that correct?

A. **Yes.**

Q. Is it okay if we just refer to that

company as Pharma Medica for today's purposes?

A. **That's perfectly fine.**

Q. If you'd be so kind as to tell us what Pharma Medica is, and what it does?

A. **Okay. Pharma Medica is a contract research organization that does clinical trials for pharmaceutical companies. So, basically they give us the medication, which would be a generic or a reference product. And they do bioavailability studies. So we administer the medication to a population that is specific to getting that one. It could be a general population. It could be a patient population, what is required for it based on the type of clinical trial it is.**

And then most of our studies are basically pharmacokinetic studies, which means that we take the blood samples to analyze the concentration of the drug in their body.

Q. Okay. And where is Pharma Medica headquartered?

A. **Pharma Medica has the headquarters is basically at -- in Mississauga in -- That's our corporate office, along with our analytical the lab.**

Q. Mississauga, where is that?

A. **Mississauga is, again, a suburb, just west of Toronto.**

Q. Okay. In Canada?

A. **In Canada, yes.**

Q. All right. And I apologize. I should've asked you earlier: Have you ever given a deposition?

A. **No, first time. So that's why I was seeing how this is all set up.**

Q. All right. If at any point in time I ask you a question that you don't understand what I'm asking, just feel free to tell me, and I'll be happy to rephrase it for you. Okay?

A. **Sure. Thank you.**

Q. Okay. If you want take a break at any time, just let me know, and we'll take a break, as long as there is no questions pending.

A. **Definitely.**

Q. Okay. Okay. Any questions so far?

A. **I tend to nod my head and all instead of answering. So just let me know to speak up the answer.**

Q. She'll hit you, if you do that.

A. **All right.**

(Whereupon, an off the record discussion was held, which by direction was not stenographically reported.)

Q. (BY MR. WENDLER) Okay. Did you do anything, Dr. Khan, to prepare for the deposition today? Did you read anything?

A. **I reviewed some of the pictures, and the videos, and briefly look at the -- over-viewed the SAE report.**

Q. Reviewed the what?

A. **The SAERs, serious adverse event report.**

Q. Anything else?

A. **No. The general SOPs, and procedures, and all the stuff is there; right?**

Q. All right. You also attended, I believe by telephone, the deposition of my client, Mr. Wallace; is that correct?

A. **No.**

Q. You did not?

A. **Only Dr. Jordan.**

Q. You attended the deposition of Dr. Jordan by telephone; correct?

A. **Correct.**

Q. All right. Did you bring anything with you, sir, to the deposition pursuant to the deposition notice?
A. **No.**
Q. All right. Now, have you ever --
Well, strike that.
How long has Pharma Medica been in business?
A. **'97, so 22 years.**
Q. All right. Can you tell us how that all came about? What prompted the formation of Pharma Medica?
A. **I joined Pharma Medica in 2004. So, it was already up and functional at that time.**
Q. All right. And when you say you joined Pharma Medica in 2004, how did that come about? Were they just looking for someone with your qualifications and you applied, or did you know someone, or how did this happen?
A. **No, I applied.**
Q. All right.
A. **So basically, as far my background, I'm a physician from back in India. I completed my Bachelor of Medicine, Bachelor of Surgery in 2001,**

worked in India for a year, moved to Canada on immigration. Then I started looking for jobs. And I started working with another CRO, Biovail, and --
Q. Another CRO what?
A. **Biovail. Another CRO called Biovail in Toronto at that time.**
Q. Biovail?
A. **Yes.**
Q. And what is CRO?
A. **Oh, clinical research organization.**
Q. All right. Sorry. And go ahead. Continue. You started working for the other CRO called Biovail?
A. **And at that time, I was a screening technician. So the responsibilities were basically collecting blood, doing ECGs, vital signs, and all of those ones. And it was a contract position only for three months. So to start it; right?**
But I used to be actively applying at other places, hospitals, doing interviews, other CROs and all. And then among all of them, I applied at Pharma also. And I was called in for an interview. So I went and gave the interview. I was hired as a quality control associate. And then from there I

moved up to my current position.
Q. And you do not have a medical degree from any U.S. --
A. **No.**
Q. -- medical school; do you?
A. **No.**
Q. Do you have a medical degree from any Canadian medical school?
A. **No.**
Q. All right. Now, your medical degree is from India. Is it -- What's the difference between the medical schools in India and the United States in terms of age requirements, and duration?
A. **U.S., I think it's around four to six years. In Canada, also, after you finish your grade 12, you can go and start. However, once you complete a medicine program in India, for Canada and for the U.S., you have to take the qualifying exams. So, there is one, two, three phases of qualifying exams for both Canada and the U.S. Once you complete the qualifying examination, you have to do your internship where you can start up. So, basically you don't have to do the whole course again. You just have to do the certification or the qualifying exams.**

Q. Let me break it down, because my question wasn't really clear. In India how old do you have to be to get into medical school, or is there an age requirement?
A. **You have to finish your grade 12, which is at least 18 years of age. Yes.**
Q. All right. So you can go straight from high school into medical school?
A. **Yes.**
Q. That's not the same as it is in the U.S.; is it?
A. **U.S., I think there is a longer program that you have to do.**
Q. Right.
A. **Maybe six years --**
Q. Okay.
A. **-- you do that.**
Q. Okay. And then in India how long does medical school last?
A. **It's four and a half, plus one year. So that's five and a half years. But in order to get to the medical school, you do have to take an entrance examination.**
Q. In India?

A. **In India, yes.**
Q. All right. And you said you practiced in India as a licensed medical doctor for how long, one year?
A. **Approximately a year.**
Q. All right. And during that one year, did you draw blood from patients?
A. **Yes. Basically doctors do not do much. But yes, we do draw blood and all. There is cases say where some of the patients request us to do it, and we do it. We do it.**
Q. Did you say doctors do not do much?
A. **Not for the blood draws. It's basically it's the nurses. In India it's the nurses. In Canada and all it's the technicians who come and do it. In India it's basically nurses.**
Q. All right.
A. **But doctors, yeah, especially when we are interns, we do a lot so that we get the experience of what arterials need to be drawn, what tests need to be ordered, and we -- The nurses tend to order -- Like you need to attend to the patients; right? You need to be with them. And definitely they'll appreciate when you yourself are attending to them a**

lot more.
Q. Well, how old were you when you came to Canada?
A. **You ask. It's been back so far. So I came in 2003. So I will be -- '76, '75 born, so five. Around 28.**
Q. Twenty-eight? All right. Back to Pharma Medica --
A. **Twenty-seven, 28.**
Q. What is your title at Pharma Medica?
A. **Vice-president clinical operations.**
Q. Vice-president clinical operations?
A. **Yeah.**
Q. And what does that entail? What are your job duties there?
A. **So basically I look after our clinic location. There are two locations in Canada. We have a clinic location, and then we have the head office, or the corporate location.**
The clinic location basically deals with all the clinical activities where we have subjects or volunteers who come to participate in the study. So we have a screening department. We have a recruiting department. We have the clinics where the subjects

come and stay. And then the supporting departments along with them, like the kitchen, the admin people, the facilities and all. So all of these activities take place at the clinic.
So all the departments in the clinic, basically I oversee all the functions, which includes the clinic staff, technicians, the group leader, the study coordinators, the screening department, which is again the technicians, screening coordinators, managers, recruiters, and the kitchen staff, and cleaning and all.
Q. All right. And this case is about what transpired at Pharma Medica's St. Charles, Missouri clinic. You're aware of that; right?
A. **Yes, sir.**
Q. Were you in charge of that at the time these studies were initiated?
A. **So basically I used to oversee both the sites. However, in 2015, mid 'til almost 2017, I was more based in Canada. I had a senior director who was over here at this site, Louis Co. He used to oversee the clinical activities.**
Q. And who was that?
A. **Louis Co.**

Q. Louis Co?
A. **Yeah. Yes.**
Q. And he's no longer with Pharma Medica; is he?
A. **No. No. No, he's not.**
Q. All right. Do you know, sir, was the St. Charles Pharma Medica clinical operations governed by the same policies and procedures as the Canadian Pharma Medica clinic?
A. **They were very, very identical.**
Q. Okay.
A. **But there are some procedures which are slightly different because of the local laws from Missouri, and the U.S. and all. Not much in regards to the clinical activities, but more like the human resources policies, and the narcotics, and all of that stuff.**
Like, for example, in the U.S. or Missouri, you can have the narcotics in the pharmacy, and then you have the licenses for Schedule I, II, and III.
In Canada it's totally different. It's a qualified person in charge who keeps it separately and manages it. So those are the slight differences.

Q. Okay. The slight differences that you're talking about between the Canadian Pharma Medica clinic and the St. Charles, Missouri clinic, would you agree they have nothing to do with what this lawsuit's about, the differences?
A. **Yeah, I agree.**
Q. You agree?
A. **They should be very, very similar.**
Q. All right. My client's Mr. Ian Wallace. Did you ever meet him, or ever talk to him?
A. **I can say yes, I have met him. Maybe during the studies, prior to the 4109 and 3952, before that, talked to him; could've spoken to him about any of the study issues.**
Like I do a lot of procedures on the side myself, too, like asking questions, consent, and these things and all. So in the course of the study, yes, I would have spoken.
Q. All right. Let me ask you this: Do you have an independent recollection of Mr. Wallace? If he walked in the door today, would you know him?
A. **Yes, I think I should be able to.**
Q. Okay. Do you have an independent recollection of anything Mr. Wallace said to you, or

to anyone else --
A. **No.**
Q. -- that you heard?
A. **No, I can't.**
Q. Do you have an independent recollection of anything you said to Mr. Wallace?
A. **No.**
Q. All right. And back to Pharma Medica, who else --
Strike that.
Are you a part owner of Pharma Medica?
A. **No.**
Q. Okay. You are just an employee?
A. **Yes.**
Q. Are you an officer or director of Pharma Medica?
A. **I'm the vice-president. So --**
Q. So, yes, you are?
A. **Okay.**
Q. All right. Who actually owns Pharma Medica? I realize it's a corporation. But who are the shareholders?
A. **I know our president and CEO, Latifa Yamlahi, and Mohammed Bouhajib, who is also VP of**

biomedical lab. Then Mike Panahi. I think he's a silent partner.
Q. And they all reside in Canada?
A. **Yes.**
Q. You don't have a U.S. medical degree; correct?
A. **Correct.**
Q. Do any of the Pharma Medica owners have a U.S. medical degree?
A. **No, I don't think so. I don't know.**
Q. All right. So you were telling us earlier with the business Pharma Medica is, and correct me if I'm wrong, but Pharma Medica works on a contract basis with pharmaceutical companies to test and gather data for testing pharmaceuticals that the pharmaceutical companies want to try to market at some point. Is that a fair summary?
A. **They do a comparative bioavailability study, which shows that the generic and the reference product -- The reference product's already marketed and approved by a similar --**
Q. I'm sorry. Can you repeat?
A. **So we do a bioavailability comparative studies. So where you compare a generic one, a drug**

product, with a reference product, which is already approved and marketed.
Q. Okay.
A. **In that way.**
Q. All right. So, if you take a pharmaceutical drug that's already on the market with a brand name, your company does the testing of the generic equivalent?
A. **Both of them.**
Q. Both?
A. **So, we don't do any placebo trials. So, when we have a population of subjects, for example, in 4109 they were receiving a drug product, which is a test product, the one that is generic, and they are receiving the other one that's a reference product already in the market. So half of them will get the test. Half of them will get the reference. And in the next period, they will switch over. This is a standard bioavailability comparative studies. Some of them could be parallel, which they only get half and half.**
But where we compare over here the concentration level of the drug are similar or not to the ones in the reference one.

Q. Okay. And you said that Pharma Medica has a facility currently, a clinical facility in Canada, and headquarters in Canada. Does Pharma Medica have any locations in the United States currently?

A. **We had a site, which is not operational anymore, in St. Charles. The site was closed. So right now only the facility is there, the building is there.**

Q. Only what?

A. **Only the building is there. There's no operations over there.**

Q. Does Pharma Medica own that building?

A. **Yes.**

Q. All right. So, there are no Pharma -- Strike that.

There are no Pharma Medica clinical facilities in operation in the United States currently; is that correct?

A. **Correct.**

Q. Okay. I think that covers all the Pharma Medica questions I had for you about the company.

So let me ask you this: In this particular case, do you have any opinions that relate to this lawsuit?

A. **I don't know about -- What do you mean by opinions?**

Q. Well, do you have -- Distinguished from a fact. For instance, you know Pharma Medica tested Mr. Wallace. That was a fact. Do you have any opinions about any sources for his contraction of Hepatitis, or do you have any opinions about the operations, or the procedures? Do you have any opinions at all relative to this case?

A. **I would say no. For us, it's basically what is the source documentation, and the procedures, and the practices.**

Q. I'm sorry. After you said no --

A. **I don't have any specific opinions on any of this portions.**

Q. Well --

A. **I can relate, and let you know the details on the procedures and the practice, what was done, and whatever is documented basically.**

Q. All right. Do you know Dr. Heather Jordan?

A. **Yes. She's -- She was our principal investigator at St. Louis -- at the St. Charles location.**

Q. All right. And I think you said, correct me if I'm wrong, you listened in on Dr. Jordan's deposition testimony; correct?

A. **Correct.**

Q. Is there anything that Dr. Jordan said in her deposition testimony that you think is incorrect?

A. **No.**

Q. Did you have a chance to read Mr. Wallace's deposition testimony?

A. **I think I read it long back, but I don't recall much.**

Q. Okay. As you sit here today, is there anything that you can remember in reading Mr. Wallace's deposition testimony that you think is incorrect?

A. **Can you go through it?**

Q. I don't think we have that much time. But as you sit here today, is there anything he said that you can recall was --

A. **I think there was a comment about -- I don't know whether it was Mr. Wallace or his brother, about reusing needles. That has never happened at Pharma Medica, used needles.**

And drawing blood in the dark and all.

That never happens. We don't do that.

And what else? Staff don't know what they're doing? Interns don't know what they're doing? No, that's not correct.

Q. Okay. Anything else that Mr. Ian Wallace, or his brother, Cody Wallace, said in their depositions that you think is wrong?

A. **I didn't prepare by the depositions. Reusing using needle sticks, that doesn't happen. Drawing blood, chaos and all. There is not chaos. We are very well organized with the -- what you call -- our procedures, especially blood sample collection, processing of blood samples. Our documentation is very clear and organized.**

Now, we always have a backup. Like, if -- We're dealing with human beings. Things can change, and all this stuff. So we always make sure that we have extra staff on hand to encounter any issues that can happen. Like, for example, a sampling difficulty. Or if someone is not feeling well, we have medics on-site. We have quality control on-site to make sure the procedures are being done correctly, to make sure the documentation is being done correctly, and in a timely manner.

Yeah. So I don't think we are not organized. We are very, very well organized, as much as we can be, anyone can be.

Q. All right. Is there anything else that Mr. Ian Wallace said in his deposition, or that his brother, Cody Wallace, said in his deposition that you think is incorrect, Dr. Khan?

A. **Of all the things I can recall, these are the things that stand out. Now, definitely, if you want me to read through the one, then I can go through it, and I can say more.**

Q. No. I just want to know the ones that you can think of as you sit here today?

A. **These are the ones thing I can think of, these are the ones.**

Q. All right. And I guess I should've asked the question earlier. You said that you read Ian Wallace's deposition. I'm assuming you also read Cody Wallace's deposition --

A. **I did.**

Q. -- based on your answers; correct?

A. **Yeah.**

Q. Okay. Did you get a chance to read the deposition of Dr. Jordan?

A. **No, I did not.**

Q. Okay. You indicated that Pharma Medica does not reuse needles?

A. **We do not. They are discarded immediately.**

Q. Yeah. And the reason --

A. **It's not just a reused needle. Even if the cap comes off, right, accidentally. If a staff takes off a cap, and they don't use it, it still goes in the biohazard. It's not left open.**

Q. And you understand that the reason you don't want to reuse needles, or you don't want to use a needle if the cap came off, because there's a potential health hazard there. Someone could become infected with a blood-borne pathogen; am I right?

A. **It's -- Universal precautions dictate that, first and foremost, you take all the precautions possible; right.**

Q. And that's one of them; right?

A. **Yeah. You do not reuse a needle. No matter what, you don't. Beat it, you discard it. You do not keep it open, not just for blood-borne pathogen. You don't know if the needle is going to be sitting open over there. How long am I**

considering this sterile? How long is it going to stay? No. Even if it's one second, discard it immediately.

Q. Okay. And you understand that the reason those rules exist is for the safety of the people who might get stuck with the needles; correct?

A. **It's -- Yes. It's the safety of the subjects who are volunteers, and of our staff, too.**

Q. Okay. And the staff, as well?

A. **Yes.**

Q. That's a good point.

And the participants in the Pharma Medica studies, participants like Mr. Wallace, they have to go through a screening process before they can become a participant in the study; is that correct?

A. **Correct. Yes. They have to go through a recruiting questionnaire, a screening process, which includes a medical history questionnaire, medical conditions, any allergies, and all those details.**

Q. Uh-huh.

A. **Along with a physical examination, blood tests, vital signs, and all, ECGs and everything. So whatever general we can encompass, it's done.**

Q. All right. And if a patient --

Strike that. Strike that.

If an applicant or participant like Mr. Wallace going through the screening process to get into one of the studies tests positive for Hepatitis C, what happens?

A. **So, the procedure is basically if anyone tests positive for any of the infectious conditions, or of the infectious communicable disease, we are obligated to inform. First and foremost, inform the volunteer itself, saying regard these results --**

Q. Inform who, sir?

A. **The volunteer himself, or the subject.**

Q. Okay.

A. **We use it replaceable, volunteer or subject. We don't use patient because very few trials are under patients. They're healthy individuals; right? So, we either use volunteer or subjects.**

Q. Okay.

A. **Volunteer sounds better.**

And we inform them, first and foremost, saying, 'This is the report that we got. This is what our doctor has evaluated, and this is what our doctor's suggestion is.'

Also, as far the requirement, we are supposed to inform the local authorities.

Q. And when you say blood-borne pathogen, that includes Hepatitis C; correct?

A. **Blood-borne conditions are infectious or communicable diseases basically. So anything like Hepatitis, HIV, tuberculosis, or anything like that would come through, we have to inform them.**

Q. All right. So if a participant -- I'm sorry. You said volunteer, or --

A. **Volunteer, yeah. Participant, volunteer. It's subject, these three.**

Q. Subject gets through the screening process, does that necessarily mean the subject does not have Hepatitis C?

A. **Again, Hepatitis C, HIV, and all of these conditions, they all have, as for my general knowledge, have a window period; right? Immediately after getting infection or something, you do not get a positive result immediately. Unless you do a vast majority of tests and all, you don't. There's a window period, and the window period varies. It's also known as incubation period. It can vary anywhere between two to eight weeks.**

So if the participant was tested in that duration of time, in between that window period, they will, or they will most probably not test positive.

Q. All right. So it's possible that one of the applicants to one of the studies went through the screening process, and tested negative for Hepatitis?

A. **(Witness nodding head.)**

Q. But it was in the incubation period, and the study, the participant actually had the Hepatitis virus in his blood, but it just was not in large enough quantity to be measurable or readable; is that correct?

A. **It could be, but a lot of our subjects come back regularly.**

Q. Yes.

A. **So if they came back afterwards, they would have been tested positive. And again --**

Q. Yes.

A. **-- we do not -- It's not only the specific test for, as in the case of Mr. Ian Wallace; right? At the end of the study, which was approximately three to four weeks, maybe five weeks after his screening appointment, we did a post-study labs in which we found the liver enzymes were high; right?**

So definitely you will be able to see something else with others, too; right?

Q. Okay. Back to my question, though. We know by the time of the second study that is at issue in this case, and that is the study --

A. **4109.**

Q. 4109, correct. We know by the time of that second study that Mr. Wallace could not have had Hepatitis C when he tested for the first study, when you screened for the first study; am I correct?

MS. DREW: Object to the form.

Q. (BY MR. WENDLER) Because the incubation period had already expired, and he was negative; am I right?

MR. MCBREARTY: I'll object to the form of the question; assumes facts not in evidence; assumes -- and also calls for an expert conclusion, which may be beyond the scope of this witness's education and training.

MS. DREW: Join.

You can answer.

A. **Quick thing: I don't remember the dates of the previous study also. And when were the screening done for the study? When were the labs**

done? Again, the incubation period could be there. So I cannot comment on that.

Q. (BY MR. WENDLER) Okay. Well, regardless, you said the incubation period is anywhere from two to eight weeks; am I right?

A. **Yeah. There are some scholars says two to 10 weeks also.**

Q. All right.

A. **Some say four to six weeks also. It's varied.**

Q. So Mr. Wallace, on January 1 tests negative for Hepatitis C, and 10 weeks go by, and he's still negative for Hepatitis C. We know that as of January 1 he did not have Hepatitis C; am I correct?

MR. MCBREARTY: Object to the form.

MS. DREW: Object to the form of the question; misstates the evidence.

Go ahead. You can answer.

A. **You can't say. Human beings are different. Some might manifest in a week, two weeks, 10 days. There's always exceptions.**

Q. (BY MR. WENDLER) Okay.

A. **You know that our body could be a full**

inverse also. Your heart, instead of being on the left side, could be right also.

Q. All right.

A. Everyone is different.

Q. Well, let me ask it this way.

A. And you cannot draw a specific conclusion like, 'Oh, January 1st is eight weeks. Okay. You were clean on that.' You can't.

Q. Okay. Well, you told me earlier that it was two to eight weeks for the incubation period. Then you said -- -

A. Yes.

Q. -- some scholars say up to 10 weeks?

A. Yeah. Some say four to 10 weeks, four to six weeks. It varies.

Q. What's the maximum?

A. I have no idea.

Q. The longest incubation period? You don't know?

A. No, I don't know that answer.

Q. Okay. All right.

Well, do you have any indication, sir, in your mind that Mr. Wallace did have Hepatitis C before the 4109 study?

A. As for --

MS. DREW: Object to the form of the question; calls for a legal conclusion, and expert opinion.

Strike that.

Object to the form of the question; calls for expert opinion beyond the scope of this witness's disclosure, and education, and training.

Subject to that, you can go ahead and answer, if you know, Doctor.

MR. MCBREARTY: Join.

A. What was the question? Sorry.

MR. WENDLER: I'll just have the court reporter read it back for us so we don't have to repeat the objections.

A. Oh, okay. Sorry.

(Whereupon, the requested portion of the record was read back by the court reporter.)

A. I cannot comment. I don't know. Because basically what all tests we did, there was nothing on it.

Q. (BY MR. WENDLER) He tested negative for

all those?

A. We only tested a specific one, Hepatitis antibody test.

Q. Okay. And he was negative for that; correct?

A. On the test, yes.

Q. Okay. Now, earlier you told us, Dr. Khan, that Pharma Medica does not draw blood in the dark. And you disagreed with Mr. Wallace's testimony, or his brother's testimony to that effect. Is there some reason you would not want to draw blood in the dark?

A. First and foremost, our procedures are very, very standard and strict. We have to ensure that we take the correct sample from the correct person at the correct time. Now, over all of these things, these are SOPs. The first priority is always subject safety, which is the volunteer, participant safety, and the staff safety, too. Handling in the dark, you cannot ensure safety.

Q. It's not a safe thing to do; is it?

A. Yeah. So it is never done in the dark. We instruct -- We do have studies where the blood draws are done in the night. So we turn on the

lights. Like, for example, the last blood draw could be at 11:00, then could be a blood draw at two o'clock in the morning.

Q. Okay.

A. So we turn on the lights in the clinic area where the bloods are drawn. And then 15 minutes before, we go wake up the volunteers or the participants saying, 'Your blood draw is starting.'

We don't wake up all of them. We wake up the ones that are at that time. Like, for example, the B group and all, and say, 'Your blood draw is starting. Please make sure you come in. Have a seat at least a few minutes before your blood draw.'

And then it is conducted exactly in the full light with the staff supervision with all the universal precautions as with all the blood draws, be it night or day.

Q. Were you actually at the Pharma Medica St. Charles facility during the blood draws that were the subject of the studies that we're here about today? Were you actually present when those blood draws were --

A. No, I was not present for both of these studies.

Q. Okay. Now, you said that the blood should not be drawn in the dark. Is it also correct that the blood should not be drawn from a patient who is sleeping, or from a study participant who is sleeping?

A. So, what we do is we inform the participants that this drug could cause sleepiness, 'You could be sleepy by this drug.' Now, certain medications where they could be sleepy, or if there could be any possible potential side effects, like your blood pressure could fall down because it's a blood-pressure lowering drugs and all, we conduct them on hospital beds, or where the subjects are on the beds, and all the stuff. And the staff goes to them, and collects the sample.

Now, we do give them a schedule of all the time points the blood samples are going to be collected. For example, you are told, 'Your sample is going to be at every hour from seven o'clock in the morning until 3:00, and then every two hours.' So you know exactly where the time is.

And at the time of blood sample collection, the staff will wake them up --

Q. Okay.

A. -- saying, 'Sir, I am going to be collecting your sample. Let me know if you're okay.'

Q. The staff is supposed to wake the participant up at the time of the blood draw; correct?

A. Wake the participant up, and get an acknowledgement meaning saying, 'Yes. Go ahead.'

Q. Okay.

A. Now, sometimes they are sleepy. They'll say, 'Yeah. Go ahead.' So -- But staff will get that from them, verify the arm band, verify the time, verify the information, everything on the tubes and all, and then collect the sample.

Q. Okay. Now, is it prohibited that if the participant says, 'Yes. Go ahead,' when he or she is woken up, is it prohibited for the phlebotomist, or the employee of Pharma Medica to proceed with drawing the blood, if the participant falls back asleep?

A. No. If they give the consent and say yes, it will be within the same minute, or the minute prior.

Q. All right.

A. But at that time, if the staff notices something is happening to the subject or the

volunteer, they'll withdraw the needle immediately, if it's noted they're not feeling well.

Q. Okay. And that's the rules, that's the procedures, that's the protocol that the employees at Pharma Medica at the St. Charles facility were supposed to follow; correct?

A. Will follow, yes.

Q. And that was for the safety of the participants, as well as the staff; correct?

A. Yes.

Q. All right. Now, let me ask you this: If you found out that one of the employees of Pharma Medica had violated one of those rules, one of those safety rules, and was reusing a needle on two participants, what would the ramifications be?

A. This has not happened. Like at least in the years I have been there, I have never heard about it. And what I've heard, nothing has happened like that before.

If anyone risks the safety of the subject, or integrity of study data in Pharma Medica, we have a code of conduct, and according to which the employee will be immediately terminated.

Q. So if an employee is caught reusing a

needle on two patients, whether it's intentionally or by accident, if they're caught doing that, they're fired immediately; is that correct?

A. If they are, yes.

Q. All right. How about if an employee at Pharma Medica is caught drawing blood in the dark, is that also in violation of the code -- What did you say, the code of ethics, or the code of conduct?

A. Either.

Q. I'm sorry?

A. There is no exception. They will be terminated.

Q. So if one of the Pharma Medica employees that's drawing blood does it in the dark, and gets caught doing that --

A. That has --

Q. -- that person is fired, as well; right?

A. They're -- Again, this has not happened. That's what I'm trying to say. If in case they do anything like that where they are risking the subject's safety, and the staff safety also, they're violating our code of conduct.

Q. Okay. And you say this has not happened. That's based on information relayed to you since you

were not there; correct?
A. **Yes.**
Q. If one of your employees at the St. Charles facility learns about another employee violating one of these safety rules, and is using a needle on two patients, is that employee supposed to report that to someone, if they learn that some other employee's doing this?
A. **So, at every time we conduct a blood sample collection, there is always two staff who is doing it.**
Q. Uh-huh.
A. **Okay. Along with that, we always have supervisor on site.**
Q. Okay.
A. **Which is a flow leader, or the group leader we call it, that is there to supervise. In case the group leader or supervisor is not there, there is always a senior person, which would be a quality control associate, or a study coordinator, or a medic always present.**
Q. Uh-huh.
A. **They will ensure that, God forbid, even before the staff does it, they will ensure they're**

doing all the steps accordingly. For example, making sure you're changing the gloves. As soon as you collect the sample, you're discarding the needle off. You're pulling the tube off. So it's not that they will wait until it's happened to report to us, they will stop it prior to happening.
Q. All right. Well, let's assume that one of the employees learns from another employee that a third employee broke the rule, and was using a needle on two patients, on two participants. Is that employee supposed to report that to someone --
A. **Yes.**
Q. -- to Dr. Jordan, or you, or someone else?
A. **They have to report immediately.**
Q. To whom?
A. **To the senior person that's on-site. So if it's a group leader, if it's a coordinator, or if it's me or Dr. Jordan, they have to be reported to every one.**
Q. So the senior leader on-site would be the person that these reports are supposed to be relayed to --
A. **Yes.**
Q. -- correct? And at any given time at the

St. Charles facility when Dr. Jordan was there, was she the senior leader on-site?
A. **The coordinators will be there. The study coordinators were in charge, along with the group leaders. And they will ensure that this information is passed on to Dr. Jordan, myself, Louis Co, and all of that stuff, along with HR.**
Q. But the chain of command is that they're supposed to report it to the study coordinator, who then reports it to Dr. Jordan --
A. **So --**
Q. -- and then she reports it to you? Is that how it works?
A. **No. So basically what happens is the technicians and the group leaders, they will report to the supervisor. But they always include myself, Louis Co. And I think, at that time, it was more of Louis Co because I was not there on-site. Louis Co and Dr. Jordan will be informed in paddle all the time.**
Q. How are you notified since you weren't there? Would you get an e-mail? Would you get --
A. **I would get an e-mail if any issues like that happened, definitely. I will get a phone call.**

Q. Okay.
A. **Definitely.**
Q. Now, let me ask you this: If one of the employees learns that another employee's violating one of these safety rules, and is reusing the needles, or drawing blood in the dark, can that employee be fired for not relaying that information in the chain of command like you just described?
A. **That employee, first and foremost, if anything like that, even if rumors come of it --**
Q. Yes.
A. **-- like talking gossip, it will be investigated totally.**
Q. That's not the question, though.
Can the employee who learns of this information, can that employee be fired by not relaying the information to the supervisor, or the study coordinator, or the chain of command like you described it a few minutes ago?
A. **So again, we have to investigate. And then basically we have to look into with HR saying 'How serious is this one? Did the employee intentionally try to withhold information, or was missed, or was not informed properly?' Then**

evaluate. But if it's intentional, yes, they will be terminated.
Q. All right. So if an employee intentionally withholds that information, that employee can be fired?
A. (Witness nodding head.)
Q. Correct?
A. Yes.
Q. All right. You mentioned something earlier that the needles are never left exposed with the cap off; right?
A. (Witness nodding head.)
MS. DREW: You need to answer yes.
A. Oh, yes. Sorry. Yes. Sorry.
Q. (BY MR. WENDLER) And why is that?
A. As I said, it's not safe to leave them open. They could have accidental finger-prick injury, not just for the subject, even for the staff. They might try to handle it to move it, and all that. So, don't. So if you have removed the cap, and then you're not using the needle, put the safety cap on, and discard it immediately.
Q. Okay. Are the Pharma Medica employees, are they also screened for blood-borne pathogens

MS. DREW: Yeah.
Q. (BY MR. WENDLER) In Missouri?
A. Yes.
Q. And what was the subject of that case?
A. I think it was an accidental fall. The case went on, and it was dismissed; right?
MS. DREW: Yeah.
A. Dismissed.
MS. DREW: Dismissed with prejudice. Andrew Walker.
MR. WENDLER: Walker?
MS. DREW: Filed in St. Charles County.
MR. WENDLER: St. Charles County?
MS. DREW: Yes.
Q. (BY MR. WENDLER) Did you testify in that case, sir?
A. No, I was not -- I did not.
Q. All right.
MS. DREW: Plaintiff was pro se, and it was dismissed by the court.
MR. WENDLER: I'm assuming by that, you defended?
MS. DREW: I defended it, and there

before hiring?
A. No. I don't think it's allowed under Missouri laws, or something like that.
Q. Okay.
A. They're not screened for any of these conditions.
Q. Now, the St. Charles Pharma Medica office, the clinical office that we're here about today, I understand that office closed down for business approximately January of 2019; does that sound right?
A. Correct. Yes.
Q. Why did that facility close?
A. I would say it was a business decision, like amount of business, and what we had to manage both the sites. So it was basically a management, senior management decision to close our Pharma Medica location.
Q. So it was attributable only to just the loss of business?
A. Yes, the business.
Q. Okay. Has Pharma Medica ever been sued before, to your knowledge?
A. I think there was a case prior, 2015 or something like that. Yeah.

was no payment.
Q. (BY MR. WENDLER) Dr. Khan, although you are a medical doctor licensed in India?
A. Yeah.
Q. You understand that there was no physician-patient relationship between you and Mr. Wallace; am I correct?
A. Yeah, I know.
Q. Am I correct?
A. You're correct, sir.
Q. All right. You told me earlier that you have probably spoken to Mr. Wallace, but you don't have any independent recollection of that. How is it that you know you've spoken with him?
A. I do meet a lot of volunteers or subjects in the clinic. I spend a lot of my time in the clinic with them, with the subjects, addressing any of their questions, or things that they have. Also ensuring with the staff being present to show what the procedures they are conducting are according or not.
Q. All right.
A. So I spend a lot of time. So there could have been instances. I speak to a lot of subjects, a

lot of them.
Q. At some point in time you learned, before this lawsuit was filed, correct me if I'm wrong, that Mr. Wallace had been diagnosed with Hepatitis C; am I correct?
A. **Correct. Yes.**
Q. All right. When did you learn of that in relation to the actual diagnosis?
A. **I think it was in between. Most probably, I would say, around the time that he was admitted in the hospital, and he was hospitalized. Around that time, I would say.**
Q. That's the Anderson Hospital in Maryville, Illinois you're talking about?
A. **Somewhere in Illinois, yes. Maryville, Anderson, yeah.**
Q. So you learned about his --
A. **Around that duration of time.**
Q. All right. You learned about his Hepatitis diagnosis around the same time --
A. **Yeah.**
Q. -- that he was in Anderson Hospital in Maryville, Illinois?
A. **Basically I was informed. I was aware of**

that. I was not informed when his initial labs were done saying they were slightly off and all. We asked for repeat. No, they don't. However, when anyone is hospitalized and all --
Q. Uh-huh.
A. **-- they will let me know.**
Q. Okay.
A. **I think the Hepatitis diagnosis came in afterwards, after he was hospitalized. When he came back, discharged, then he came back to the clinic, did the repeat tests at that time. So, I was informed about him being hospitalized, and the diagnosis of the Hepatitis C came in afterwards.**
Q. All right. Well, I'm trying to pinpoint, as closely as we can, the time frame that you learned of the diagnosis, or the potential diagnosis?
A. **Yes.**
Q. Was it while Mr. Wallace was in Anderson Hospital that it was reported to you?
A. **That he has Hepatitis?**
Q. Yes.
A. **That was after.**
Q. It was after?
A. **Yeah.**

Q. Okay.
A. **Only when we got the labs and all.**
Q. All right. And that would've been within a week or so of him being in Anderson Hospital?
A. **I don't know. I have to check the dates exactly.**
Q. Well, let me ask it this way: After you learned Mr. Wallace had been diagnosed with Hepatitis C, after the positive lab results came back, did you make any attempt to reach out to Mr. Wallace and talk to him?
A. **No.**
Q. Okay. Why not?
A. **Well, our staff at the site was already following up with Mr. Wallace. And Louis Co, the study coordinators were already following up with him. And had Dr. -- Dr. Jordan had gone and seen him, and visited. So I said that was sufficient. I don't want to be -- That's too much, if more people do it; right?**
Q. All right. So --
A. **I think that was sufficient.**
Q. And how did you learn that Dr. Jordan went to Anderson Hospital?

A. **I think Louis Co had informed me over the phone.**
Q. Okay. Did Mr. Co tell you that he went to the hospital also?
A. **Yeah. I think he mentioned both of them had gone, or he had driven Dr. Jordan, or something like that, yeah.**
Q. Okay. But this was after the fact, after the hospital visit that --
A. **Yes.**
Q. -- you were notified; correct?
A. **Correct. Yeah.**
Q. Okay. Let me switch gears a little bit now. I am going to hand you what we will mark as Exhibit No. 1. Let's just start with the 4109 study.
A. **Okay.**
(Whereupon, Plaintiff's Exhibit No. 1 was marked for identification by Mr. Wendler.)
Q. (BY MR. WENDLER) Are you familiar with this document, sir?
A. **Yeah, this is the study protocol. Sorry.**
Q. Yes. And this is for the study for the

Roxane Laboratories product; correct?
A. **Correct.**
Q. Did you have any hand in drafting this? What do you call this, a protocol, or a contract? What do you call this?
A. **This one is the protocol. This is the study protocol that we conduct the study accordingly with. Now --**
Q. Did you have any hand in drafting this document, Exhibit No. 1?
A. **I would say no.**
Q. Who drafted it, do you know?
A. **So, basically --**
MR. MCBREARTY: Off the record.
(Whereupon, an off the record discussion was held, which by direction was not stenographically reported.)
A. **So basically the drafting of the protocol is -- comes in from what the sponsor wants, sponsor requirements, along with our scientific affairs team.**
Q. (BY MR. WENDLER) Your sign what?
A. **Scientific affairs team at the corporate**

location. They review --
Q. I'm still not understanding. Your signed what?
A. **Scientific affairs.**
Q. Scientific affairs?
A. **The department over there.**
Q. All right.
A. **They look at that, what are the guidelines of the recommendations for conducting trials. What are the requirements, age, sample collection, what time should it be taken, along with the principal investigator. They all review it together, and draft it. I do look at most of the protocols. I don't think I did this one, because this one was the one that we had done quite a few times, in order to looking at the feasibility, and the logistics of the studies.**
(Whereupon, Plaintiff's Exhibit No. 2 was marked for identification by Mr. Wendler.)
Q. (BY MR. WENDLER) Okay. Let me hand you Exhibit No. 2. And this is the protocol for the study for the --

A. **Pseudo --**
Q. -- protocol 3952, bearing Bates number 168.
MR. MCBREARTY: Thank you.
Q. (BY MR. WENDLER) Are you familiar with Exhibit No. 2?
A. **Yeah. I had reviewed this protocol earlier. I'd gone through it.**
Q. Okay. All right. And with regard to Exhibit No. 2, that's the study --
A. **3952.**
Q. -- for the Tris Pharma --
A. **Correct.**
Q. -- study; correct?
A. **Yes.**
Q. All right. Did you have a hand in drafting, or participating in the drafting of the Exhibit No. 2, the Tris Pharma protocol?
A. **No, I don't think so. Not that I can remember.**
Q. I want to ask you some questions about both of these studies combined. And rather than ask the same questions over and over, I'm going to ask you about these Exhibits in the singular rather than

the plural. Okay?
A. **Okay.**
Q. But the same questions will be applicable to both studies.
Okay. First, the guidelines that are created for these, for the study, who creates those guidelines?
A. **So, basically the scientific affair team, along with our protocol writing team.**
Q. The scientific affair team at Pharma Medica?
A. **Yeah. They review the F.D.A. guidelines.**
Q. Okay.
A. **What is there previously, if F.D.A. had issued any guidelines on conduct of these studies and all. They'll review those guidelines, along with the -- consultation with the sponsors.**
Q. The sponsor? And in this case, the sponsor for Exhibit No. 1 would be --
A. **Is Roxane.**
Q. -- Roxane Laboratories; correct?
A. **Yes.**
Q. And the sponsor for Exhibit No. 2 protocol study would've been Tris --

A. **Tris.**
Q. -- Pharma; correct?
A. **Yes.**
Q. All right. The sponsor, you said, has some input in creating the guidelines; correct?
A. **Not the guidelines. Guidelines are provided by the F.D.A.**
Q. All right.
A. **All right. Any other studies specific design and all, the sponsor will have an input. It's their study.**
Q. For example, what does the sponsor --
A. **Well, if the sponsor says that, 'Oh, I want to include -- what do you call -- people or volunteers over the age of 55 --**
Q. Okay.
A. **-- to 60.' Then our scientific affairs team will check and say, 'No. The guidelines state that it has to be up to 50 only.'**
Q. Okay.
A. **So we substantiate that, and tell them that, 'These are the guidelines. So we are stopping at 50.'**
Q. Okay. So the sponsor can create

specifications, and Pharma will do it, Pharma Medica will do it, provided it's within the F.D.A. guidelines; correct?
A. **Within the F.D.A. guidelines, yes.**
Q. So the sponsor can determine things such as age of the participants; correct?
A. **Yes.**
Q. Okay. And the sponsor can determine when blood is to be drawn?
A. **No. I don't think the sponsor can determine when the blood is drawn, unless they have data with them. If they have done previous trials, and which indicates that you need these sampling time points and all.**
Q. Yes.
A. **So they can tell us like, 'You know what? We have done trials. This is the data we have for these time points. This is where we found deficiency. And we want to add these time also into it, or remove time lines in those specific matters.'**
Q. By way of example, the sponsor can say, 'We want the blood samples to be drawn every hour on the hour.' By way of example; am I right?
A. **If they have data supporting that, and if**

it's in agreement with -- What do you call --
Q. F.D.A.?
A. **-- F.D.A. guidelines.**
Q. Okay.
A. **Then, yes.**
Q. All right. And reading through the protocol, it looks like the sponsor also has some input on when the patients are allowed -- are allowed to eat? I said patients. I meant participants.
A. **So basically it's not allowance to eat. It's, again, F.D.A. guidelines says for the bioavailability studies; right?**
Q. Uh-huh.
A. **If it's a fed study, they're evaluating concentration of the drug when the drug is taken on a full stomach.**
So F.D.A. has specific guidelines. Actually, they state how much concentration of carbohydrates, fats, and protein should be there. They should be taking it within 30 minutes. So there are very specific guidelines.
And also, these guidelines state that for the majority of the studies, they have to be fasting for at least -- what do you call, four hours.

Q. All right.
A. **So the most engaging portion is basically the time of the duration that they're fasting before and after.**
Q. Okay.
A. **Other than that, it's regular times.**
Q. Okay. If you could look at Exhibit No. 1, sir, turn to Page 10, Bates number 361. Where it says Table of Contents, do you see that?
A. **Yes.**
Q. All right. And then on Exhibit No. 2 --
A. **Uh-huh.**
Q. -- on Page 15, again we have a Table of Contents. I want to ask you about those.
A. **Sure. Page 15?**
Q. Fifteen, right. It's Bates numbered 0182.
A. **Okay.**
Q. What we're looking at in the Exhibit is Table of Contents for the study protocol; correct?
A. **Yes.**
Q. And who actually created this study protocol? Who printed it out? I see the Pharma Medica logo on the top of the page, but who actually printed this out?

A. **Printed it out, or completed it, how it would be approved, and reviewed, and signed, and then distributed?**
Q. I'll go with your question. It's much better.
Who printed it out, created it, and approved it?
A. **Okay. So, it's different levels again. We have a separate team called the protocol writers.**
Q. Uh-huh.
A. **So they are the ones who complete and draft the protocols. And you will see there is a page -- Is it after the Table of Contents? Over here, key personnel and facilities, you'll see there the name of the protocol writers on it.**
Q. Okay. And who is the key personnel protocol writer?
A. **The protocol writer for this is Erangi.**
Q. And is that a Pharma Medica employee?
A. **Yes.**
Q. What is his name, or can you -- Erangi? What's the last name?
A. **Tennakoon.**
Q. Okay. And again, he works for Pharma

Medica?
A. **Yes.**
Q. And there's also a person here listed --
A. **The vice-president of quality assurance.**
Q. Radu?
A. **He's the vice-president of scientific affairs, the department I was telling you, scientific affairs.**
Q. This is on Exhibit No. 2; correct?
A. **Yes.**
Q. All right. Exhibit No. 1, who were the key personnel?
A. **The protocol writers was Arun Mehan. The vice-president of quality assurance was Mary Stipancic. Vice -- Senior vice-president of scientific affairs was Dr. Radu Pop. Then again, vice-president of laboratory operations, Mohammed Bouhajib. Our clinical trial director, Latifa Yamlahi. And principal investigator, Dr. Heather Renee Jordan.**
Q. All right. And all of those individuals, with the exception of Dr. Jordan --
A. **Dr. Jordan.**
Q. -- work at Pharma Medica headquarters in

Canada; correct?
A. **I think Dr. Radu is retired.**
Q. Okay.
A. **Okay.**
Q. Did he work at --
A. **He worked --**
Q. -- Pharma?
A. **-- at headquarters, yes.**
Q. Okay. Now, the document that we have in front of us, with regard to the Table of Contents, it appears that this document gives parameters, and instructions, and definitions on a whole bunch of key areas. If we look at -- There's a study design section. Do you see that?
MS. DREW: Which document? Which Exhibit are you using?
MR. WENDLER: It's in both.
MS. DREW: Okay.
Q. (BY MR. WENDLER) Section 8.0 says study design.
A. **Yes.**
Q. Do you see that?
A. **Yes.**
Q. All right. And then there's a next

paragraph, or next entry below design says interval between doses.
A. **Okay.**
Q. So this document regulates the time in between doses of the drug that's being tested; correct?
A. **Correct.**
Q. And then was Section 8.7 says study population. That's where the geographic characteristics --
A. **Yeah.**
Q. Not geographic.
Strike that.
That's where the demographic characteristics of the participants are regulated and restricted; correct?
A. **Are indicated, yes.**
Q. All right. Next Section, 9.0, subject selection, talks about general screening, how the subjects are to be screened prior to participation or entry in the study; correct?
A. **Correct.**
Q. And there is the screening procedures that sets out the procedures that are to be followed for

the screening process; correct?
A. **Correct.**
Q. And the inclusion and exclusion criteria, that sets forth how someone can be admitted or not in the study; correct?
A. **Correct.**
Q. And then it even regulates methods of contraception? In Section 9.5, it says effective methods of contraception; correct?
A. **Correct.**
Q. So that regulates, if a female is involved and she's using a contraceptive, this regulates participants, depending on the type of contraceptive devices they're using; correct?
A. **Yes. So basically it indicates what they should be using --**
Q. And not using?
A. **-- during and after the study, yes.**
Q. All right. And then the next section, 10.0, study procedures, and it has restrictions, and housing, and test procedures at check in, all of these things are regulated and governed by this contract, or this protocol; correct?
A. **Correct.**

Q. It talks about administration of food and fluid. That's also regulated by the protocol?
A. **Yes.**
Q. The study drug administration, that's also regulated by the protocol; right?
A. **Correct.**
Q. What's the next category, 10.6?
A. **Concomitant treatment.**
Q. What's that about?
A. **So in case if any person is not feeling well, they need to administer any medication and all, what is allowed, what is not allowed. Again, if any medication has to be given, it has to be given.**
Q. All right.
A. **Right. If -- That basically applies to, also, if the subject is taking any medication, any concomitant medication is allowed during the study for them to take.**
Q. Fair enough.
This protocol regulates, it says posture and physical activity. Is that posture and physical activity of the participants?
A. **Yes.**
Q. All right. And then the next section

deals with health status monitoring, and vital sign measurements, and ECG monitoring. That's all regulated --
A. **Yes.**
Q. -- during the study by this protocol; right?
A. **Correct.**
Q. And then there's a category called end of study procedures. Is that for when it comes time for the participants to be released from the study?
A. **Yes, when the study is completed.**
Q. There is a section called criteria for removal from the study. Again, that sets out the parameters that when participants should be removed?
A. **Correct.**
Q. There is an adverse events section; correct?
A. **Correct.**
Q. And there's a procedure for reporting adverse events; correct?
A. **Correct.**
Q. And what Mr. Wallace had here was, in fact, reported as an adverse event; correct?
A. **Correct.**

Q. And then there's a category called study documentation that regulates how the documents for the study are to be compiled and stored; correct?
A. **Correct.**
Q. And then Section 17.0, it says safety evaluation?
A. **Uh-huh.**
Q. Right?
A. **Yes.**
Q. What is that about?
A. **Let me see.**
Q. Well, I looked at it, and it says under, safety evaluation in the protocol, Section 17.0, the first sentence says, "There be will no formal evaluation of safety or tolerability." So, I am a little bit confused.
A. **So --**
Q. What does the safety evaluation deal with?
A. **For some studies, right, for this one there was no evaluation in between the study, or at the end of the study. There are certain studies like drug-drug interaction studies, those -- escalation studies, single ascending dose, multiple ascending dose, SAD and MAD they call it. These studies have**

the safety evaluation. So, especially like the dose escalation studies where you do a portion of the study, you give a particular dose, evaluate the safety data. And then after that evaluation is done, then you go into the next step. If there is going to be another dose added, or the dose increased or decreased. So these kind of studies will have the safety evaluation.

Now, for all our protocols, there is a standard template so we know exactly what is where. Even if there is no safety evaluation, there is still a sentence will be there. The paragraph will be there to mention that.

Q. All right.

A. **So this is basically applicable in dose escalation studies.**

Q. Well, on Paragraph 17.0, it says there will be no formal evaluation of safety or tolerability.

Strike that. Let me just rephrase it.

Paragraph 17.0 of the protocol, under the heading of safety evaluation states in the first sentence, "There will be no formal evaluation of safety or tolerability." Did I read that correctly?

A. **Correct.**

Q. Now, next sentence says, "An assessment of safety will be based primarily on the frequency and severity of AEs." Correct?

A. **Correct.**

Q. AVs -- I'm sorry. AEs are adverse events; correct?

A. **Correct.**

Q. So was there an assessment of safety based on the reporting of Mr. Wallace's adverse event, if you know?

A. **I'm not aware of that. I don't know.**

Q. All right. Okay. If you turn then to Section 18.9 of the protocol?

A. **Insurance.**

Q. Are you with me?

A. **Yeah. Insurance; right?**

Q. Yes. It says insurance. Now, it says for the purpose of study-related injury of subjects, the sponsor will have valid insurance for the duration of the study, and for at least 30 days after the end of the study. Do you see that?

A. **Yes.**

Q. And it says PMRI, which is Pharma Medica; right? Correct? PMRI is --

A. **Yes. Pharma Medica Research, correct.**

Q. Will have valid liability insurance at all times subjects are at the clinical facility; correct?

A. **Correct.**

Q. It's been claimed that Pharma Medica had no insurance to cover Mr. Wallace's injuries in this case. Do you know if there is insurance?

A. **I'm not aware of the insurance policies and all.**

Q. Do you know why there was no insurance policy since it looks like --

A. **No. I don't if it's there or not. But I am not aware of that much. This is something that I don't deal with.**

Q. Okay.

A. **The insurance and all, it's the, yeah, project management team that handles it.**

Q. All right. But you do agree that protocol required the provision of insurance?

A. **Yes.**

Q. Okay. And whether there was insurance or not, you don't know?

A. **There should be. But --**

MS. DREW: For the record, there was insurance procured, and they denied the claim.

MR. WENDLER: Oh.

MS. DREW: They have insurance. They had insurance in place. But when the claim was submitted, the carrier denied the claim based on the exclusion. I am not involved with the insurance side of it --

MR. WENDLER: Okay.

MS. DREW: -- with the denial of the claim.

MR. WENDLER: Well, that's news to me. That answers that question. You don't know why it was excluded?

MS. DREW: No.

MR. WENDLER: Or why it was denied?

MS. DREW: No. All I -- I can look. I believe it's Berkeley, but I can -- I can find out which carrier it was submitted to.

MR. WENDLER: Uh-huh.

MS. DREW: And during the pendency of this matter, I believe when you filed it initially in St. Charles, at some point there was a determination made by the carrier that there was no

coverage. And all I received was an e-mail saying, "You do not need to include me any longer. We have denied the claim."

MR. WENDLER: Okay.

Q. (BY MR. WENDLER) Just so I have covered myself here, Exhibit No. 1, that sets forth the parameters of the protocol and testing procedures for the Roxane Laboratory study that Mr. Wallace was in; am I correct?

A. **Correct.**

Q. And Exhibit No. 2 sets forth the parameters, and restrictions, and protocol for the testing that Mr. Wallace participated in for the Tris Pharma study; correct?

A. **Correct.**

Q. All right. Do the sponsors of the Pharma Medica studies have the right to audit the records --

A. **Yes.**

Q. -- of Pharma Medica? And do the sponsors have the right to monitor the studies?

A. **Yes.**

Q. I've been informed that there was actually video cameras at the St. Charles Pharma Medica facility that enabled people from the outside to

monitor via video feed; is that accurate?

A. **No.**

Q. No?

A. **There are cameras in the clinics, and on the periphery outside and all to monitor the facilities, the subjects, and the staff. But these are not continuously watched by anyone. If there is any issue, or any -- an issue comes in, like, for example, subject compliance, staff issue, any theft, or any damage, or anything like that, then a -- what do you call -- a specific request would be made.**

This request has to be approved by our C.E.O. to say that we would like to have a feed, video feed of that particular clinic, or that particular location to see if we have.

Now, myself, IT, and Louis Co, we did have access to the cameras, but we would not sit and watch the videos at all times. No one from outside could watch it. So what our role was, if they say, 'Oh, we notice the freezer door was open.' Or, 'We noticed something was spilled in that location.' So what we do is we can go into that location, check the cameras, inform the IT saying, 'Based on the incident or the report that came in, which was approved,

please provide or save a feed of that particular camera for that day, that time.'

Q. Okay.

A. **But no one from outside can see it, no.**

Q. All right. So none of the sponsors have access to the video monitoring?

A. **If there are any issues, then if it's required, the sponsors will communicate with the project management, and with the C.E.O., or our clinical trial director, and then our team will look into it, and if they need to provide it for the sponsor, they can provide for that.**

Q. All right. So how far back can you go back and capture video?

A. **I think it's -- I might be wrong, but I think it's approximately four weeks.**

Q. Okay. Well, let me ask you this: When Mr. Wallace reported he had Hepatitis C --

A. **Uh-huh.**

Q. -- did anyone make any attempt to go back for the prior four weeks, and capture any of that video footage of the testing, or whatever was going on at Pharma Medica in St. Charles? Did anyone do that?

A. **No. Because our procedures are very much in place and strictly followed, along with the universal precautions. So, there is no need to suspect that anyone could have ever done anything like that. They were not.**

Q. Okay. To make sure I have this correct, you told us earlier that you have the ability to --

Strike that.

You told us earlier you had the ability, at the St. Charles facility, to go back and capture video from four weeks back; am I right?

A. **Yes.**

Q. But after Mr. Wallace reported that he had contracted Hepatitis C, no one, at that point in time or thereafter, made any attempt to go back and capture the prior four weeks of video footage from the Pharma Medica facility; am I correct?

A. **Correct.**

Q. All right. You said that the people that had access to the video feed were you, Louis Co, and the IT director; correct?

A. **IT department.**

Q. IT department? And is that up in Canada?

A. **Yes.**

Q. And who is in charge of the IT department?
A. **Our VP of IT, Mohammed Yamlahl.**
Q. Did I see his name on one of these contracts?
A. **No.**
Q. What did you say his last name was? Yam ---
A. **Yamlahl. That's Latifa.**
Q. So Latifa Yamlahl has the same last name?
A. **Yes. It's a sister.**
Q. Latifa is his sister? Okay. And Mohammed is the brother of Latifa?
A. **Yeah. Yeah.**
Q. Okay. And who all is in the IT department under Mr. Mohammed Yamlahl in Canada?
A. **There is John Ross. There is Mircea Vlad.**
Q. Can you say that one again?
A. **Mircea, M-I-R-C-E-A. John Ross, I already mentioned. Mircea Vlad. Mircea.**
Q. Last name?
A. **Vlad, V-L-A-D.**
Q. Vlad? Okay.
A. **Vlad. And there is Amir, A-M-I-R, Khaatan, K-H-A-T-T-A-N. And there is a David Li,**

L-I, I think. Yeah. I think there is one or two more. There are at different locations. So I don't know all the staff there. But those are the ones I usually communicate and all.
Q. And were all these people, Mr. Ross, Ms. Vlad, Mr. Khaatan, Mr. Li, and the one or two more, were they all employed in the IT department with Mohammed ---
A. **Yamlahl.**
Q. -- Yamlahl during the time frame when Mr. Wallace was being a participant in the St. Charles studies that are at issue?
A. **I don't know about David. I don't know when he started. This is from 2016; right?**
Q. Yes.
A. **So I don't know when David -- Maybe, maybe not.**
Q. Okay. But the IT department consisted of, at any given time, one, two, three, four, five -- at least five individuals; correct?
A. **Four to five, yes.**
Q. Four to five individuals? Do they work around the clock there?
A. **There are standard hours, but they are**

always available.
Q. Well, back during the time frame of these studies, did Pharma Medica have any other study facilities, other than the St. Charles facility, and the facility in Canada for clinical studies?
A. **No, we only had two sites.**
Q. All right. Did all of these people in the IT department have the ability to watch the video feed in realtime?
A. **I don't think so. I think only maybe a couple of them maybe. I'm not for sure, but I think Mohammed, John, and Mircea, I think.**
Q. Okay.
A. **Because you asked me for the IT department; right? It's pretty big. They have developers and all that stuff to look after in house. But basically for any issues with the, I guess, hardware and all, I think it's mostly Mohammed, Mircea, and John Ross.**
Q. And does John Ross and Mircea still work there?
A. **Yes.**
Q. All right. And again, I apologize if I've asked this.

A. **Uh-huh.**
Q. This is at the headquarters facility --
A. **Correct.**
Q. -- in Toronto? Okay.
Louis Co, where is he these days?
A. **He joined another pharmaceutical company called BioPharma Research. Yes. BioPharma Research.**
Q. When Ms. ---
A. **It's BioPharma Medical Services, I think, yeah.**
Q. When Dr. Jordan testified, she said that she had entered into a severance package contract with Pharma Medica. Do you know anything about that severance package agreement that she had?
A. **No. Dr. Jordan reports to -- directly to our C.E.O.**
Q. Okay.
A. **So, no, I don't.**
Q. All right. Did Dr. Jordan ever report to you for anything?
A. **No. We worked together. We always worked hand-in-hand. Like I would always consult with her. She would always consult with me. Being the PI, and then me being now the clinic portions, and the clinic**

setting, we always worked together. But she didn't report to me.
Q. Okay. When you said you always worked together, is that when you were physically present with each other?
A. No. We would always talk, discuss. I used to ask a lot of advice from her.
Q. Okay.
A. And then she would ask me about procedures, like, 'Hey, can we do this?' But we always were in constant contact.
Q. Okay. Do you have any knowledge, Dr. Khan, with regard to why Pharma Medica chose to use needle sticks for blood draws rather than catheters? Do you know why?
A. So because catheters -- catheters have -- F.D.A. does not approve a device that is used on a catheter called a mandarin or an obturator.
Q. I'm sorry. You said that the F.D.A. does not approve the use of catheters for --
A. It approves the use of catheter. But a catheter, you cannot leave it open. You have to close it; right?
Q. Right.

A. So there is a specific device that is used in Europe and Canada called as an obturator. So, if this is a catheter, you put the obturator in there, and you close it. F.D.A. does not approve the use of the obturator in U.S.
Now, the other option for using a catheter is to keep on flushing it, introducing either Heparin or a saline flush. We are not that particular, and it's not recommended for the scientific team to always introduce saline flush, and what do you call -- to use Heparin flush also, especially when it's healthy individuals.
Q. All right.
A. Okay. So that's the reason why we cannot use it. If F.D.A. approves it, we'll use it.
Q. Okay.
A. Or we would have used it.
Q. Is there any prohibition against using catheters for blood draws in studies such as are at issue here?
A. There is no prohibition, but because it's not F.D.A. allowed, we cannot use it.
Q. Well, if it's not F.D.A. allowed --
A. The obturator is not approved by F.D.A. to

be used on the catheter. That's why we cannot use it.
Q. But the Heparin flush is allowed?
A. I don't think Heparin flush is allowed.
Q. Okay. Let me ask you this: Are you aware whether or not catheters are allowed to be used in the U.S. for pharmaceutical studies such as at issue here?
A. You can use catheters, provided saline flush or the Heparin flush is allowed.
Q. All right. And do you know which is more costly, or more expensive to use, the catheters or the needle for blood draws?
A. I would say they are both the same.
Q. Okay. Do you know specifically why Pharma Medica did not use catheters rather than the needle for blood draws?
A. Yeah. Because the obturator and the flush were not approved.
Q. Not approved by?
A. The obturator are not approved to be used over here in the U.S. And then we did not have the approval to use the flush, saline flush.
Q. Did not have approval to use the saline

flush by whom?
A. By scientific affairs team, and also with the drug. So if the drug concentrations are going to be affected by saline flush, no, you cannot use it.
Q. Okay. So what you're saying, correct me if I'm wrong, is the scientific affairs and the sponsor did not approve the use of the catheters; correct?
A. And the flush.
Q. With the flush?
A. Yeah.
Q. Okay. And scientific affairs is Pharma Medica; correct?
A. Correct.
Q. All right. So in order to use the catheters, both would have to agree to it? The sponsor would have to agree to it, and the scientific affairs department at Pharma Medica would have to agree to it; correct?
A. Yes.
Q. All right.
A. Now, there are certain studies, certain agencies which only strictly ask for catheters to be used. For those ones, we would use bags. For these

ones, we can't.
Q. So you have used catheters for studies when the sponsor called for it?
A. **When the regulatory agency where it was being submitted called for it.**
Q. Fair enough.
Okay. Do you know which is safer to avoid blood-borne pathogens like Hepatitis C, that is the needle draw or the catheter? Which is safer?
A. **Overall for safety perspective --**
Q. Uh-huh.
A. **-- in my opinion, there might be different schools that might think and all, not to avoid -- as long as you take universal precautions, they both are safe. My personal preference would be needles are much safer.**
Q. You think needles are safer?
A. **(Witness nodding head.)**
Q. Yes?
A. **Yes.**
Q. Okay.
A. **Safety-wise, needles.**
Q. Do you know, sir, in Missouri for the St. Charles clinic whether there is a special certificate

or license necessary to use catheters?
A. **No.**
Q. Do you know, one way or the other?
A. **I don't think there is a special certificate or license in Missouri to use a catheter.**
Q. Do you know if there is a special certificate or license required in Missouri to work as a phlebotomist?
A. **Hold on. Let me go back to the previous one.**
Q. Sure.
A. **To use a catheter, there is no specific license. But in order to insert a catheter, you have to be either a medic or a nurse, and -- Yeah. All else, you have to be at least IV certified.**
Q. You have to be what certified?
A. **IV, intravenous certified.**
Q. And that's not required for the needle sticks?
A. **Needle sticks, they need to have a phlebotomy certificate, or certified phlebotomy completion.**
Q. All right.
MR. WENDLER: Let's take five. Take

a break.
(Whereupon, a brief recess was taken.)
MR. MUDGE: We are back on the record, and the time approximately 10:24.
Q. (BY MR. WENDLER) Dr. Khan, at the St. Charles Pharma Medica facility, is it true that there were timers that were present to regulate the time allotted for blood draws per participant?
A. **No, we did not have timers to regulate the blood draw. We had clocks --**
Q. Fair enough.
A. **-- to document the time samples was collected.**
Q. But there was not an allotted time limit for a person to draw blood, and if they couldn't get it done, for instance, in one minute, the next participant moved into the seat?
A. **So, basically everything was scheduled. It was all scheduled.**
Q. Uh-huh.
A. **Every procedure the person would do would be scheduled based on the scheduled dosing time. So if a person is scheduled to be dosed at seven**

o'clock, and the blood draws are every hour, for example, the person is scheduled to be dosed at 7:01, the blood draw is supposed to be, as per the protocol, collected hour -- every hour, then the scheduled times would be 8:01, 8:02 -- Sorry. 8:01 9:01, 10:01.
Now, it is always preferred to draw the sample on the minute. However, if you are not able to draw the sample on the minute, no matter for whatever reason, it's a sampling difficulty, or the subject was in the restroom, or they're late to come in, then what we would do is we would send them over to a backup table where they'll be a -- backup staff would be present. They would collect the blood. Whatever time it was collected would be documented.
Q. Okay.
A. **So there was no restriction that, oh, you have to take the sample at 8:01. If you don't take the sample, sample is missed. No.**
Q. So how is it determined when the person goes to the backup table?
A. **So, basically the way the tables are set up, there is two staff on each table. So if this is a table, there is one staff here, and one staff over**

here. All the odd numbers will come on that side, all the even numbers will come.

So, number one, if his sample time is 8:01, he will come on that side. Then staff A will collect that sample at 8:01.

Q. Okay.

A. Okay. Number two will come over here to the second staff to be taken at 8:02. Then a third person would come to staff A. So they have two minutes in between.

Q. Okay?

A. That should be sufficient to collect a single tube.

Q. So how was it then determined whether the person goes to the backup table --

A. So --

Q. -- if they can't get the blood, for whatever reason, within that time frame?

A. So there are two different scenarios at this time. So if subject number one comes to staff A, and staff A gets ready, puts on the gloves, takes a needle, tube, verifies all the information. And 8:01, he goes in, could not collect the sample. The vein might have collapsed --

Q. Okay.

A. -- or anything at that time. So then he will take it off. It will still be within in the same minute, or possible. He will take it off, close with a cotton ball, or Band-Aid, or whatever, and then send the person over. Because he tried, he could not get it.

Q. That's when they go to the backup table? That's scenario number one?

A. Scenario number one.

Q. What's the second one?

A. The second scenario is, okay. Everything checked. 8:01, you push the needle in. The tube starts filling. However, if it takes more time for the tube to fill in, the vein is small, the amount of blood coming into the tube is slow. But he already has the blood flow established. At that time, he realizes, 'You know what? I'm already off my minute.' Though, he's taking the sample. 'I might be getting late for the next person.'

Q. Yes.

A. So either he or the supervisor, the person who is over the QC or the GL, they will call the person over. 'Okay. Number three, you come over

here. Staff A, you carry on with your blood draw.'

Q. Okay.

A. So they will take -- So these are the two scenarios that would happen.

Q. Do you know how many video cameras there were at the Pharma Medica facility in St. Charles?

A. I don't know the actual count.

Q. Are they still there?

A. I think they should be there. I don't know if all of them are there or not, but they should be there. Most of them should be there.

Q. Okay. Do you know if the video cameras were situated such that they would actually capture the blood draws?

A. No, the cameras would not capture the blood draws. I would say there were approximately three to four cameras in each -- I am trying to think; right? Three to four cameras in each clinic. One would be in the dosing area where we administer the medication. And there would be one to two in the main area where the subjects are seated. Not specifically focused on the blood draw tables, no. They'll be in the general area. And there would be at least one in the processing area where the staff

separated the plasma and stored it in the freezers.

Q. But to your knowledge, there were no video cameras pointed to the area where the blood draws were done; am I correct?

A. Not exactly. They would take a broader area, but not focusing on the blood draw tables, no.

Q. Okay. When you say broader area, did it encompass the area --

A. It could.

Q. -- where the blood draws were done?

A. It could.

Q. Okay. Did you ever make a phone call to the St. Charles Pharma Medica facility to report something that you saw on a video feed?

A. No. I was asked to check. So, I would go in and check. And then I would see if the -- ask IT to save the video. But not monitor, and then look at the camera, and say, 'This is wrong.' Oh, no.

Q. Okay.

A. I would not -- We would not sit down and watch videos.

Q. So if you saw something wrong on a video that you observed, you would ask them to save that so that it could be used for what, instructional

purpose?
A. **Yes. If I would see anything as a part of if I'm looking at something else, like why the samples were put in late or something, documentation is missed, or something like that. And while seeing that, if I see anything like that, I would ask them to save a portion of that clip.**
Q. And so why were the video cameras installed to begin with?
A. **So basically it's multiple reasons. So, monitoring the subjects, safety monitoring of the subjects, too.**
Q. Okay.
A. **Along with subject, staff safety, along with the perimeters outside. PMRI assets; right? Any theft, any break-in, any damage. And also study data, study documentation is there in the clinic. Our samples are there in the freezer rooms and all. So to monitor all of those things, God forbid something happens.**
Q. Did you ever have to do any of the firing of any employees at the St. Charles Pharma Medica facility?
A. **I would be consulted, definitely, if**

anyone's employment has to be terminated.
Q. Okay.
A. **We'd always do it with the presence of HR. And I would always inform our clinical trial director, our president, and C.E.O. And, yes, there are instances where I was present for some of them. And at some points where I was consulted, and I give my opinion saying, 'Yes, I think the employment has to be terminated.'**
Q. Were any of the phlebotomists ever terminated?
A. **Yes, we did have some who were terminated.**
Q. For what reasons?
A. **Various reasons.**
Q. And a phlebotomist is a person who specializes in drawing blood; correct?
A. **Collecting blood sample, yes.**
Q. All right. When you say for various reasons, what various reasons?
A. **I think the biggest issue we had was reliability, or attendance.**
Q. Okay. Any other reasons you can think of?
A. **No, not for the phlebotomists over here.**
Q. Okay. What do you know about the training

of the phlebotomists that were hired by Pharma Medica?
A. **So, we have specific training department, or basically a training supervisor. He or she will basically, when the new employees come in, they will first, a couple of days, they will be with the HR, going through the overall HR orientation, which goes through it more of the policies, work-place safety policies and all, along with setting them up on the system for time sheets, and all the stuff.**
And then there's a training, who will be our group leader, who was very good with her work and all. She would take in those people. We would not take more than two or three at a time. Only after that person's, two or three individual's training are completed, then they'll go on the floor. So she will go through all the trainings.
Q. Who was this trainer?
A. **Her name was Elizabeta. Elizabeta, A-L -- E-L-I-Z-A-B-E-T-T-A, Kameric. I might not spell it correctly. It's K-A-M-E-R-I-C. She was the person who was mostly in charge with the training. However, the other GLs, supervisors would be in charge, and look after the training after that.**

Q. Is Ms. Kameric, is she employed by Pharma Medica currently?
A. **No. We don't have any staff at St. Louis anymore; right?**
Q. So she was exclusively at the St. Charles facility?
A. **Yes.**
Q. All right. Did Pharma Medica in St. Charles use any interns for blood draws?
A. **We had interns who came from schools. I think most of them were from St. Charles Community College. But in order for them to come in, the interns were basically a part of the co-op placement program of the phlebotomy course. So after they had completed in classrooms, they had a specific amount of numbers of needles they had to get, or blood collections. So, maybe 30 sticks, or 50 sticks, or a hundred sticks, something like that, based on that. After they have completed all of those programs, then they will come to us as part of placement from that college.**
Q. Well, were there any people at Pharma Medica in St. Charles who were drawing blood who had never drawn blood --

A. No.
Q. -- on a human before?
A. No. They all have to have certain number of needles or sticks, they call it, on each other, on five human beings before they come to us.
Q. So -- And that minimum number was what?
A. It varies. I think it was something, 50 or 60, but I won't be able to give the exact number, which I would have known the exact numbers and all.
Q. And who actually made the hiring decisions on the phlebotomists and the interns?
A. So phlebotomists and the interns, our supervisors, there was a supervisor was present, supervisor for lab assistants.
Q. And who was that?
A. It was my Michelle Ballwin.
Q. Okay. Who else?
A. There was also -- What is the name? I forgot her name. I'm forgetting the name. Oh, my God. He was a group leader. Well, he was -- The supervisor, Michelle Ballwin was the supervisor. And there was another person who was the assistant supervisor. When I remember his name, I will tell you for sure.

supervisor, group leader, or he was the group leader manager.
No, he's not there on this one. At that time, maybe he was part-time medic. But -- Let me go through this. These are non-managerial. Deandre, DeAndrea, Dallas, Tabron, Jasmine, Shun-Ta, Steve. No.
Q. You don't see his name on the list?
A. No.
Q. Okay. Let me ask you this: I think you told me this earlier, but correct me if I'm wrong, when the employees were hired to work for Pharma Medica at the St. Charles facility, none of them were tested for Hepatitis, or any other blood-borne pathogen at the time of, or prior to hiring; am I correct?
A. Correct.
Q. All right. Did any of your St. Charles Pharma Medica employees transfer to other shops when the St. Charles Pharma Medica shop closed down?
A. Sorry. Did they transfer to where?
Q. To Canada, or to any other ---
A. No.
Q. -- Pharma Medica facilities?

Q. I might have a list here. If I could find it.
A. He was a paramedic, and Michelle was a nurse. They would actually go over with HR to the St. Charles Community College where the interns are coming in, interview them, see how their understanding and skills are there. They would interview maybe seven, eight, or whatever are there. From those, they will select a handful, three or four, two or three.
Q. I will just hand you Exhibit No. 3 --
(Whereupon, Plaintiff's Exhibit No. 3 was marked for identification by Mr. Wendler.)
Q. (BY MR. WENDLER) --- which is the same as Exhibit No. 6 from Dr. Jordan's deposition. That's a list of the Pharma Medica St. Charles employees. If you can find that person's name on the list that you were thinking of?
A. So Elizabeta is the one -- the one I said was doing the training.
Q. Yes.
A. Andrew -- Andrew Janis was the previous

A. No.
Q. Did Pharma Medica have another facility somewhere else in the U.S. at one point?
A. No.
Q. Okay. Do you consider yourself an expert on Hepatitis C?
A. No.
Q. Do you know what the long-term health effects of Hepatitis C are?
MS. DREW: Object to the form of the question; vague.
A. No.
MS. DREW: But you can answer.
A. No.
Q. (BY MR. WENDLER) Okay. Did you have any conversations with Dr. Jordan about her conversation with Mr. Wallace at the hospital in Maryville, Illinois?
A. I think I did.
Q. What did she tell you?
A. I can't recall. I think she said she went and saw him, met him, and just asked him how he was doing. But I cannot recall the exact conversation and all.

Q. Okay. You did not tell Dr. Jordan or Louis Co to go to the hospital; am I correct?
A. **No.**
Q. Am I correct?
A. **I did not say that.**
Q. Okay. Have you seen any of the written reports by Dr. Hull regarding this case?
A. **No, I did not get a chance to see that.**
Q. Okay. I'm going to hand you Exhibit No. 4, sir.
(Whereupon, Plaintiff's Exhibit No. 4 was marked for identification by Mr. Wendler.)
Q. (BY MR. WENDLER) This is a document that was produced to us by Roxane Laboratories. It says Master Agreement. Are you familiar with that?
A. **I heard about Master Agreement, but I don't go through it with them. It's basically the project management team and the sponsor have it.**
Q. All right. Can you tell me how this Master Agreement is different from, or has -- provides different regulations than Exhibit No. 1, the protocol?

A. **So this is study specific, how the particular study and all is going to be conducted.**
Q. Exhibit 1 is, the protocol?
A. **Yes, the protocol.**
Q. All right.
A. **Master Agreement, this is the first time reading it. I haven't read it ever before.**
Q. That's fine.
A. **It's basically -- I think it's the understanding with Pharma Medica and the sponsor.**
Q. So it's your understanding that this Master Agreement that we've marked as Exhibit No. 4 provides a different --
Strike that.
Is it your understanding that the Master Agreement that we have marked as Exhibit No. 4 provides additional guidelines that Pharma Medica was to follow in the testing of Roxane Laboratories medications?
MS. DREW: Object to the form of the question; calls for speculation. Dr. Khan's already said he's never seen the document before.
MR. MCBREARTY: Join.
A. **Yeah.**

MS. DREW: You can go ahead and see --
A. **No. I have to read through it, and then let you know.**
Q. (BY MR. WENDLER) Go ahead, and skim through it, if you want, or read through it.
A. **No. No. I have to read it. It's large.**
Q. I -- This was just produced to us in discovery.
A. **Yeah.**
Q. I'm trying to figure out what it is. I thought you might be able to help me.
A. **No. Basically I don't get the Master Agreements. It's between project management and the sponsor. They have it, and they save it.**
Q. Okay.
A. **So for us, it's always the protocol that dictates the study's specific conduct.**
Q. All right. You said the Master Agreement is between who?
A. **The project management team of Pharma Medica and the sponsor.**
Q. And who is the project management team?
A. **Our director of project management is**

Marianna Colalillo, and then the other project managers who work with her. So there is Amin, Maureen. There's Joanna. There is Whitney. There is Fareen. Yeah.
Q. How many employees does Pharma Medica have?
A. **Right now in Canada we have approximately around 200-plus or so.**
Q. Did you read through the adverse event reports relative to Mr. Wallace?
A. **Yes, I had reader earlier the SAERs, adverse event report that was generated.**
Q. All right. Well, let me ask you this: When Mr. Wallace's AST was reported on June 15 at the rate of 59, do you agree that's above the normal range?
A. **Can I see the report? Because it'll have the ranges in there.**
Q. If I can find it, I'll show it to you. Let's see. Okay. We'll mark this as Exhibit No. 5.
MR. MCBREARTY: Which one?
MR. WENDLER: Bates number 422. It was Exhibit 4 from the Dr. Jordan deposition.
(Whereupon, Plaintiff's

Exhibit No. 5 was marked for Identification by Mr. Wendler.)

Q. (BY MR. WENDLER) Exhibit No. 5, that's the adverse event report; do you agree?

A. **Hold on here. This is --**

Q. Just tab that page. That's the one I want to ask you about.

A. **Yeah. But this is not the one that we completed. I think this is the one that the sponsor completed --**

Q. All right.

A. **-- for F.D.A. We drafted the other SAE report.**

Q. Okay. Well, I don't have that with me, or I don't have it handy. So let's just go with this one. On Page --

A. **Sorry.**

Q. On Page 3, that tabbed page?

A. **Let's see if the ranges are there.**

Q. Yeah. It indicates Mr. Wallace's AST was 59. What is AST?

A. **Aspartate aminotransferas, it's a liver enzyme.**

Q. Okay. You'd agree that that report of 59 was above the normal range?

A. **So this one, "No other complaints were reported during the remainder of the post-dose time frame. The subject completed his post-study lab procedures on 14th of June, 2016. Are you talking about 2014? I'm sorry. June 14?**

Q. Excuse me. She's trying to keep up with you.

A. **Oh, sorry.**

Q. You have to talk louder and slower.

A. **Okay. Are you talking about this 14 June 2016 --**

Q. Yes.

A. **-- in which AST and ALT levels were found to be elevated? AST is 59 units per liter.**

Q. Yes.

A. **With a reference range of 10 to 40.**

Q. Yes.

A. **So his value was 59. It was elevated.**

Q. All right. So it was above the normal range; correct?

A. **Yes.**

Q. All right. And that's an indication that something is not normal; right?

A. **Correct.**

Q. And what's an elevated AST liver enzyme indicate?

A. **So, it can be multiple things. Basically the liver enzymes are higher, the liver is working more. It could also be due, for example, a high fat diet. It could be multiple reasons.**

Q. Okay.

A. **So it's not specifically indicative of one. And it's very transient, too. It goes up and down pretty fast.**

Q. Fair enough.

Could a high AST liver enzyme reading be indicative of Hepatitis?

A. **It could be, but not always.**

Q. All right. On that particular date when Mr. Wallace's AST was 59, above the normal range of 10 through 40, should Dr. Jordan have reported that to you?

A. **No. Because this is a not as significantly high.**

Q. Okay. How about on the next reading where his ALT -- I'm sorry. Where is AS --

Well, strike that.

How about when his ALT was at 103 with a normal range of being nine through 46, should Dr. Jordan have reported that to you?

A. **Dr. Jordan does not need to report to me any of these things. She's the principal investigator.**

Q. Does she need to report to anyone?

A. **It's her call --**

Q. Okay.

A. **-- about this. But if I would have seen, and if any of us would have found, it would've been given to Dr. Jordan.**

Q. Okay.

A. **As long as Dr. Jordan, principal investigator, is aware of it, and she's following up with it, that's correct. Now --**

Q. What is the ALT?

A. **It's again a liver enzymes. It's alanine aminotransferase.**

Q. Okay. How about, if you turn to the next page? I believe it's the next page where it talks about the liver enzyme was -- The AST level was 253, when normal is 10 through 40. Should that have been

reported by Dr. Jordan to anyone?
A. **So, it's here at the same page.**
Q. Same page? Thank you.
A. **Yeah. Here it was --**
Q. Should that have been reported by Dr. Jordan to anyone? This is on June 21. Should she have reported that to anyone?
A. **Again, it's her call. As long as she informed the subject, the subject was informed of it and updated.**
Q. Yes.
A. **And being followed up, and if it's being done.**
Q. So there is no requirement that Dr. Jordan was to notify a supervisor, or the sponsor, or anyone that Mr. Wallace's AST and ALT levels were way beyond normal range?
A. **No.**
MS. DREW: Object to the form of the question; vague as to way beyond.
Subject to that, you can -
MR. WENDLER: I'll rephrase it.
Q. (BY MR. WENDLER) So there was no obligation on the part of Dr. Jordan by Pharma Medica

was nine through 46, again, same answer: There was no obligation for her to report that to anyone at Pharma Medica in Canada, to your knowledge?
A. **I think she would have reported it to the project management, at least.**
Q. She would have, or should have?
A. **I would say would have.**
Q. Should she have, if she didn't?
A. **I think she would have.**
Q. That's a different question.
A. **I know.**
Q. Should she have, if she didn't?
A. **Sorry. What is the question is?**
Q. Should Dr. Jordan have reported, on June 21, that Mr. Wallace's ALT level was 471, that is his liver enzymes were 471, when the normal range is nine through 46, should she have reported that to Pharma Medica in Canada?
A. **I cannot say it should be a should or not, until the protocol specifically dictates. It's again her judgment call --**
Q. All right.
A. **-- she being the principal investigator.**
Q. Well, that's what I'm trying to figure

requirements, protocols, procedures, or expectations that she report Mr. Wallace's AST liver enzyme level was 253 when the normal range was 10 through 40? There's no requirement for her to report that?
A. **I don't know if this protocol has a specific requirement like that. Some protocols do. Some sponsors have requests.**
Q. I'm not talking about the protocol. I'm talking about Pharma Medica's policies, and procedures, and requirements, and expectations?
A. **Yes. So as per this one, it's the principal investigator's decision, which is Dr. Jordan.**
Q. Totally up to her?
A. **Yeah. But certain protocols do dictate that you need to inform immediately of these increased values.**
Q. All right. And on this particular day --
A. **Sorry. I'm just going to continue.**
I don't know if Dr. Jordan informed the sponsor or the project management at this stage or not.
Q. On this particular day, June 21, when Mr. Wallace's ALT level was 471 when the normal range

out, whether there is any restrictions on her judgment call?
A. **No. Because if --- Yes. If the protocol states anything specifically, she would have, and she should have.**
Q. Okay. And if the protocol does not state specifically, there is no obligation on her part, unless she chooses to, to report to Pharma Medica that any participant's liver enzymes are extremely high; am I right?
A. **Yes, sir.**
Q. All right. So then on June 25, four days later when his AST level reached 900, when the normal range is 10 to 40, same answer: There was no obligation on her part to report that to Pharma Medica, unless it was in the protocol?
A. **I think that by due diligence, she would have reported.**
Q. She would have, or should have?
A. **Would have.**
Q. All right. And if she didn't, should she have?
A. **I think she did.**
Q. You think she did?

A. **Yeah, with these values.**
Q. Okay. And why do you say you think she did?
A. **I don't understand. I'm not sure.**
Q. Okay. If she did not report the 900 AST level liver enzyme rate in Mr. Wallace when the normal range is 10 to 40, if she did not report that high 900 range reading, should she have? Should she have reported that to Pharma Medica? And I'm talking about Dr. Jordan here?
A. **I know. I know I would have.**
Q. Okay. If Dr. Jordan did not report that, should she have?
A. **I think she should have.**
Q. Okay. Why do you think that?
A. **It's an -- It's not going down, and it's going up basically. I don't know how was the examination, or the examination done. The values are high compared to --**
Q. It's dangerously high; is it not?
MS. DREW: Object to the form of the question; vague.
A. **It's high.**
Q. (BY MR. WENDLER) Is it dangerously high?

MS. DREW: Same objection.
A. **No. I have seen higher values.**
Q. (BY MR. WENDLER) Okay. How about on the same day when his ALT level was 1,800, when the normal ranges was nine through 46, should Dr. Jordan have reported that to Pharma Medica on June 25?
A. **I would say she should have.**
Q. Okay. Do you know if she did?
A. **I can't recall.**
Q. All right. Now, let me ask you this: When Mr. Wallace talked to Pharma Medica, he was asked to come in for a fourth round of tests on June 26 rather than go to the nearest emergency room, despite all of these levels and readings that we just went through. Do you know why he was told to go back to Pharma Medica in St. Charles rather than go to the nearest emergency room?
A. **Okay. We always advise the subjects, first and foremost, whenever we follow-up with them --**
Q. Uh-huh.
A. **-- to make sure how they're feeling first.**
Q. Okay. Yes.
A. **'Are you feeling all right? Do you have**

any problems? We did your repeat. The repeat is high. It is not going down. It is high. How are you feeling? If you are not feeling well, immediately go to your nearest hospital or emergency department.'
Q. That's what's required?
A. **Yes.**
Q. That's the protocol; right?
A. **Yes.**
Q. All right.
A. **And that's always what we tell them.**
Q. Yes.
A. **Okay.**
Q. That's what should happen?
A. **And we say -- What do you call? 'And also if you're feeling all right, if everything is fine, can you drop by for a -- to the clinic to do the repeat test, and see our doctor. You can always come back to the clinic. You can always come and see our doctor. But keep in mind your safety is your first priority.'**
Q. Yes.
A. **'So always seek medical attention immediately, if you're not feeling well.'**

Q. Okay. So do you know if Mr. Wallace was told, 'Do not go to the nearest emergency room.'?
A. **I wouldn't --**
Q. And he was told instead to go back to Pharma Medica for a fourth round of tests on June 26? Would that be contrary to your expectations for the Pharma Medica facility in St. Charles, given these high readings that we went through?
A. **We would not tell anyone not to seek medical attention. So he would not be told, 'Oh, don't go to the hospital. Come us -- come to us.' No, he won't be told.**
Q. So if he was told, 'Don't go to the hospital,' that would be contrary to your expectations of the Pharma Medica employees in St. Charles; am I right?
A. **Yeah. Our employees would not say that.**
Q. Okay. Well, you kind of changed my question.
A. **Sorry.**
Q. If the employee that he spoke to told him, 'Don't go to the nearest emergency room. Don't go to the hospital. Instead come to Pharma Medica.' If that was, in fact, said to Mr. Wallace, that would be

contrary to your expectations of how the Pharma Medica employees should have treated Mr. Wallace?

MS. DREW: Object.

Q. (BY MR. WENDLER) Am I correct?

MS. DREW: Object to the form of the question; speculation; assumes facts not -- that will not be in evidence.

You can go ahead and answer.

MR. MCBREARTY: Join.

Q. (BY MR. WENDLER) Am I correct?

A. **It would be contrary to what we do.**

Q. Contrary to your expectations?

A. **Expectations. Thank you.**

Q. Yes?

A. **Yes.**

Q. Okay. What do you know about any other adverse event study reports for any other participants at the Pharma Medica facility in St. Charles, if anything?

MS. DREW: Object to the form of the question; vague; over broad.

A. **To what kind of adverse event report are you --**

MR. WENDLER: I'll just withdraw

that.

Q. (BY MR. WENDLER) Do you know of anyone else who reported positive for Hepatitis C at the St. Charles facility?

A. **I think -- I don't remember specifically the names, and dates, and years and all, but there were a few for Hepatitis C. Both at screening stage, and I think there was one post-dose also.**

Q. At screening stage, and one what?

A. **Post-dose. So, participated in a study, and tested positive at the post-study.**

Q. At post-study?

(Whereupon, an off the record discussion was held, which by direction was not stenographically reported.)

Q. (BY MR. WENDLER) Post-dose?

A. **Post-dose, yeah.**

Q. And post-dose means they got through the screening process, and then tested positive for Hepatitis C after the screening process; right?

A. **After they got study drug, they took part in the study, at the end of the study they tested**

positive.

Q. Okay. And do you know who that was?

MS. DREW: Object to the form of the question; violates HIPPA.

MR. WENDLER: I'm not asking for a name. I'm just asking does he know.

MS. DREW: Okay.

A. **I don't remember, but I can check.**

Q. (BY MR. WENDLER) Do you know when it was?

A. **20 -- Late 2016, early '17.**

Q. And do you know if that person was in any of the studies with Mr. Wallace?

A. **No.**

Q. You don't know?

A. **No. I mean that person was not in any of the studies with Mr. Wallace. Sorry.**

Q. And how are you able to determine that, if you don't know the person's name?

A. **Because most of the subjects that participated with Mr. Wallace on these two studies, I think that the personnel asked; right? We checked, and they, none of them had Hepatitis.**

Q. Okay. Have any of the Pharma Medica employees been tested for Hepatitis C, whether it's

required by Pharma Medica or not, to your knowledge?

A. **Yes. There is a procedure where we do test our staff for Hepatitis, or all of them, Hepatitis A, B, C, Hepatitis B, C, and HIV in case if we have any needle-stick injury.**

Q. Okay. And was that done at the St. Charles facility ever?

A. **No. St. Charles we did not have any needle-stick injuries.**

Q. Okay.

A. **We had a couple, I think at least three or four, in Canada in all of this duration of time where we ensure we have the consent for the staff and the subject where we do collect both the staff and subject sample to test.**

Q. You said there were three or four needle-stick injuries in Canada?

A. **To my recollection, in the past several years.**

Q. Is that during your tenure at Pharma Medica?

A. **(Witness nodding head.)**

Q. Yes?

A. **Yes.**

Q. And I'm sorry. When did you start there?
A. **February, 2004.**
Q. Okay. And in those situations where there were needle-stick injuries at the Canadian Pharma Medica --
A. **Yes.**
Q. -- clinical facility, the employees were then tested for blood-borne pathogens?
A. **So, we tested the employee and the subject.**
Q. Yes.
A. **Who -- whose needle was accidentally came in contact with the staff. We tested them for Hepatitis and HIV.**
Q. Okay. And this was -- This happened three or four times?
A. **During the whole time, yes.**
Q. Yes. Did anyone at Pharma Medica tell Mr. Wallace that his treatment would be paid for by Pharma Medica?
A. **I don't recall. I'm not aware of.**
Q. Do you know Nancy Erickson is?
A. **No.**
Q. Do you know who Andrew Aronsohn,

A-R-O-N-S-O-H-N, is? Do you know who he is?
A. **No.**
Q. You've never spoken to either of those people; have you?
A. **Nancy Erickson? No. I think the name sounds familiar, Nancy Erickson. But, no.**
Q. Okay. Do you have any marks or strikes against your medical license, sir?
A. **No.**
Q. Do you have any criminal --
A. **No.**
Q. -- history?
A. **No.**
Q. Okay. Is there anything else, sir, about this case, or about Mr. Wallace that you think is important that we have not covered in your testimony here today?
A. **No. If you want to ask me anything, or is there anything else?**
Q. Nothing?
A. **No. Sorry.**
MR. WENDLER: Okay. That's all the questions I have then. Thank you, sir.
(Whereupon, an off the

record discussion was held, which by direction was not stenographically reported.)
MR. MUDGE: We are back on the video record, and the time is approximately 11:01.
[EXAMINATION]
QUESTIONS BY MR. MCBREARTY:
Q. Dr. Khan, my name is Brian McBrearty, and I represent Hickma Labs, Roxane Labs, and West-Ward Columbus in this case. I have a very few questions for you, and they're just of a clarification manner.
If I understand your testimony correctly, all participants prior to entering the study are tested for blood-borne pathogens, including Hepatitis?
A. **Correct.**
Q. All right. In the St. Charles facility, was Mr. Wallace and one other individual were the only participants who tested positive for Hepatitis C either before or after --
A. **No.**
Q. -- testing?
A. **After participating in a study, I'm aware**

of these two, Mr. Wallace and the other person, who had completed -- who had been dosed for a study. And at the completion of the study they tested positive.
There were individuals who tested positive prior to participating. When they come in for the initial screening appointment, they were individuals who tested positive, but they did not get into the study.
Q. I was going to follow-up. They were excluded?
A. **Excluded, correct.**
Q. So they would not have been in any studies with Mr. Wallace?
A. **Correct.**
Q. And the other individual that you discovered who tested positive post-participating in the study was not involved in any of the studies with Mr. Wallace?
A. **I only checked the individuals who were with Mr. Wallace in these two studies. And they were not positive for Hepatitis at any time.**
Q. Another way of saying it is: Nobody else who was with Mr. Wallace ever tested positive for Hepatitis C?

MR. WENDLER: Objection; lack of foundation.

A. **No. I did not -- Mr. Wallace, I think, participated at least around six, seven studies.**

Q. (BY MR. MCBREARTY) I'm talking about these two studies that we're talking about?

A. **These two studies? No.**

MR. WENDLER: Same objection.

Q. (BY MR. MCBREARTY) So for those two studies, Mr. Wallace was the only one who tested positive for Hepatitis C?

A. **Correct.**

Q. Okay.

MR. MCBREARTY: Thank you. No further questions.

MR. WENDLER: A couple more questions, unless you have any, Teri?

MS. DREW: I have nothing.

[FURTHER EXAMINATION]

QUESTIONS BY MR. WENDLER:

Q. A couple more questions: With regard to the other persons who participated in these two studies that are at issue with Mr. Wallace, those persons who participated with him, do you know about

any testing those persons have undergone for Hepatitis C, outside of Pharma Medica?

A. **No. I don't know about outside Pharma Medica.**

Q. All right. And then you said that this one other person tested positive for Hepatitis C, but it was after Mr. Wallace was no longer in the study. And this is a separate study, and it was later; correct?

A. **To my knowledge, I think this was something later in 2016.**

Q. Were there any changes in the blood-drawing procedures or policies by Pharma Medica between the time of Mr. Wallace testing positive for Hepatitis C and this other person testing positive for Hepatitis C?

A. **No.**

Q. Okay. So the same policies applied?

A. **Yeah.**

Q. Okay.

MR. WENDLER: That's all I have. Thanks.

MS. DREW: We will read and sign.

MR. MUDGE: We are off the video record. The time is approximately 11:05.

* * * * * * * *

[Witness excused.]

COMES NOW THE WITNESS, SHABAZ KHAN, M.D., and having read the foregoing transcript of the deposition taken on the 7th day of November, A.D., 2019, acknowledges by signature hereto that it is a true and accurate transcript of the testimony given on the date hereinabove mentioned.

_____

SHABAZ KHAN, M.D.

Subscribed to before me this _____ day of _____, 2019.

_____

[Notary Public]

My Commission Expires:_____

I, Kimberly A. Harris, Certified Shorthand Reporter and Notary Public of the County of Madison, State of Illinois, do hereby certify that SHABAZ KHAN, M.D. came before me on the 7th day of November, A.D., 2019, at the offices of Hinshaw & Culbertson, LLP, 701 Market Street, Suite 1375, St. Louis, Missouri, 63101, and swore before me to testify to the truth, the whole truth, and nothing but the truth regarding his knowledge touching upon the matter in controversy.

I do further certify that I did take stenographic notes of the questions propounded to said witness and his answers thereto and that said notes were afterwards transcribed by computer-aided transcription under my direction and supervision. I do further certify that the attached and foregoing is a true, correct, and complete copy of my notes and that said testimony is now herewith returned.

Dated this 19th day of November, A.D., 2019, and given under my hand and seal.

KIMBERLY A. HARRIS, CSR